PART 109—STERILIZATION AND PASTEURIZATION AT LICENSED ESTABLISHMENTS

Sec.
109.1 Equipment and the like.
109.2 Sterilizers.
109.3 Pasteurizers.

AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

§ 109.1 Equipment and the like.

(a) All containers, instruments, and other apparatus and equipment, before being used in preparing, handling, or storing biological products, at a licensed establishment, except as otherwise prescribed herein, shall be thoroughly sterilized by live steam at a temperature of at least 120 °C. for not less than one-half hour, or by dry heat at a temperature of at least 160 °C. for not less than one hour. If for any reason such methods of sterilization are impracticable, then a process known to be equally efficacious in destroying microorganisms and their spores may be substituted after approval by the Administrator.

(b) Instruments which are found to be damaged by exposure to the degree of heat prescribed in this section, after having been thoroughly cleaned, may be sterilized by boiling for not less than 15 minutes.

[23 FR 10051, Dec. 23, 1958, as amended at 34 FR 18119, Nov. 11, 1969; 56 FR 66783, Dec. 26, 1991]

§ 109.2 Sterilizers.

Steam and dry-heat sterilizers used in connection with the processing of biological products at licensed establishments shall be equipped with automatic temperature recording gauges: *Provided*, That other record keeping systems may be used when approved by the Administrator. When gauges are used, they shall be periodically standardized to assure accuracy. Charts and other temperature records made during production shall be available at all times charts and records shall be kept in accordance with part 116 of this chapter.

[35 FR 16039, Oct. 13, 1970, as amended at 56 FR 66783, Dec. 26, 1991]

§ 109.3 Pasteurizers.

All pasteurizing equipment shall meet the requirements in paragraphs (a), (b), and (c) of this section and be acceptable to Animal and Plant Health Inspection Service.

(a) Metal serum containers shall be used in licensed establishments. During the heating process, each container shall be surrounded by a separate water jacket or equivalent so that the entire container, including its lid, is heated to the required temperature. Each serum container shall be equipped with a motor-driven agitator and a separate automatic recording thermometer.

(b) Each water bath shall have an automatic temperature control to limit the temperature of the water to a maximum of 62 °C., an automatic recording thermometer, an indicating thermometer set in a fixed position, and circulating mechanism adequate to insure equal temperatures throughout the bath. The heating unit for the bath shall be separated from the serum container and the water jacket.

(c) Accurate thermometers at licensed establishments shall be used at frequent intervals to check temperatures of the serum as registered by recording thermometers.

[35 FR 16039, Oct. 13, 1970, as amended at 56 FR 66783, Dec. 26, 1991]

PART 112—PACKAGING AND LABELING

Sec.
112.1 General.
112.2 Final container label, carton label, and enclosure.
112.3 Diluent labels.
112.4 Subsidiaries, divisions, distributors, and permittees.
112.5 Review and approval of labeling.
112.6 Packaging biological products.
112.7 Special additional requirements.
112.8 For export only.
112.9 Biological products imported for research and evaluation.
112.10 Special packaging and labeling.

AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 38 FR 12094, May 9, 1973, unless otherwise noted.